

## REMARKS

After entrance of the previously filed amendment, claims 12, 13, 15, 16, 21-23, 25-28, 31-36 and 51-62 were under consideration in this case. Claims 2-11, 18, 29, 30, 37, 42-45 and 47-50 were withdrawn. Applicant cancels claims 2-11, 18, 29, 30, 37, 42-45 and 47-50 as directed to a non-elected invention. Claims 12, 13, 21, 23, 35, 36, 51, 53, 55, 58, 60, and 61 are amended and claims 56 and 62 are canceled. New dependent claims 63-67 are added. Claims 12, 13, 15, 16, 21-23, 25-28, 31-36, 38-41, 51-55, 57-61, and 63-67 are presently under consideration.

### Amendment of the Claims

Claims 12, 13, 21, 23 and 51 have been amended to recite the phrase "a cell in culture" to replace "a cell." The amendment is supported by the original claims.

Claim 13 has also been amended to delete the word "yeast."

Claim 35 has been amended to recite that the recombinase is a site-specific recombinase which excises the one or more regulatory elements of the target gene. This amendment is supported throughout the specification which, the Examiner has indicated on page 6 of the current Office Action (lines 10-12), as a whole teaches the "use of recombinases to excise polynucleotide sequences (containing regulatory elements) to modulate target gene expression." Claim 36 has been amended for consistency with claim 35.

Clerical errors have been amended in claims 53 (site specific is replaced with site-specific) and claim 55 in which a redundant word "recombinase" was deleted.

Claim 56 has been canceled.

Claim 57 has been amended to depend from claim 58.

Claim 58 has been amended to be independent of claim 56, which has been canceled, and to incorporate the subject matter of claim 62, which has also been canceled.

Claim 62 has been canceled, but its subject matter is retained in claim 58 as amended.

The new claims 63-68 have been added to better claim that which the inventors consider to be their invention and are dependent variously upon claims 21, 23 and 58. These new claims are supported by original claim 16 and 28.

None of the amendments to the claims represent the addition of new matter.

### The Rejections

Claims 12, 13, 15, 16, 21-23, 25-28, 31-36, 38-41 and 51-62 are rejected under 35 U.S.C. 112, first paragraph for failure to meet the written description requirement. Applicants respectfully traverse this rejection with respect to the amended claims remaining in this case.

The recitation "cell" in claim 12 is considered to be new matter. It is believed that the rejection is intended to be applied to independent claims 21, 23 and 56.. Claims 12, 13, 21, 23, 32, 51, 58 and 60 have been amended to replace "cell" with "cell in culture." Claims 56 and 62 have been cancelled. Claims 15, 16, 22, 25-28, 31, 33-36, 38-41, 52-55, 57, 59-61 depend from one of amended claims 12, 13, 21, 23, 32, 51, 58 or 60. The amendments are believed to obviate this rejection.

Claim 13 has been rejected for the recitation of yeast which has a cell wall. Claim 13 has been amended to delete the word yeast.

Claim 35 has also been rejected because of the recitation that the "one or more regulatory elements are flanked by site specific recombination sites." The rejection is believed to also apply to claim 36 which depends from claim 35. The Examiner states

that "the specification taken as a whole described the use of recombinases to excise polynucleotide sequences (containing regulatory elements) to modulate gene expression." Based on this statement, Applicants have amended claim 35 to recite that "the one or more regulatory agents include a site-specific recombinase which excises one or more regulatory elements of the target gene, thereby modulating expression of the target gene product." Claim 36 has been amended for consistency with the amendment to claim 35 and does not now recite flanking recombination sites. It is believed that this amendment obviates the rejection of claims 35 and 36. The amendment of claims 35 and 36 broaden the scope of the claims rather than to narrow the scope of the claims.

Claim 61 has also been rejected. The Examiner indicates that topoisomerase is indicated in the specification to be a preferred linker between the translocating peptide and the regulatory element. Claim 61 has been amended to depend from claim 12 and recite that "the translocating polypeptide and the one or more regulatory agents are linked by a Vaccinia topoisomerase I linker." In view of the Examiners comments it is believed that this amendment obviates the rejection. This amendment does not narrow the scope of the claims.

This rejection has been obviated by cancellation or amendment of the claims.

Claims 56 and 57 are rejected as anticipated by Phelan et al in view of additional information that p53 (of Phelan et al.) is a DNA-binding protein. Claims 56 and 57 are also rejected as anticipated by U.S. patent 6,017,735 in view of the same information that p53 is a DNA-binding protein. Claim 56 has been canceled thereby obviating this rejection with respect to claim 56. Claim 57 has been amended to depend from claim 58 thereby obviating the rejection of claim 57.

Claims 58-60 and 62 which depended from claim 56 were not rejected over the prior art of record. Applicants assume that these claims would be allowable if rewritten in independent form to recite all of the limitation of claim 56. This amendment has been made as described above. Applicants have combined the subject matter of claim 62 into

claim 58, canceled claim 62 and rewritten claim 58 as an independent claim. Applicants have also rewritten claim 60 as an independent claim including the limitations of claim 56. Further claim 57 has been amended to depend from claim 58.

It is believed that all of claims 57-60 and 62 are now allowable.

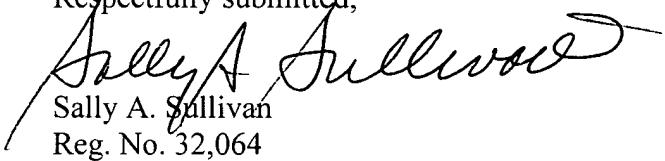
### The New Claims

In view of the apparent allowability of claims 21, 23, and 58 over the prior art of record, Applicants have added new dependent claims 63-67 directed to the use of a selected translocating polypeptide and to the use of a fusion protein of the translocating proteins and the one or more regulatory elements.

### Conclusions

The claims as amended are believed to overcome the rejections. Passage to issue is respectfully requested. The undersigned requests a telephone call from Examiner Sullivan to discuss any remaining issues in this case to expedite allowance of claims. The claims as amended contain 5 independent claims. It is believed that payment of excess claims fees for addition of two independent claims are required (\$172.00). The amendment is also accompanied by a Petition for Extension of Time of two months with appropriate fee. A total of \$592.00 in fees is submitted. If the fees submitted herewith are incorrect please deduct any deficiency or credit any overpayment to deposit account 07-1969.

Respectfully submitted,



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Attorney Docket No. 20-03  
lem:December 19, 2003